IN THE UNITED STATES PATENT AND TRADEMARK OF SERIAL NO: 09/827,493

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04/06/01

EXAMINER: JIANG GROUP ART UNIT: 1643 DOCKET: 96606/15UTI

FOR: Unique Composition of Zwitterionic \$
Phospholipids and Bisphosphonates with Reduced Toxicity and Enhanced \$
Bioavailability \$

EV 328 518 924 US

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Commissioner of Patent

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Date of Signature

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## **RESPONSE TO 7 MAY 2003 NON-FINAL OFFICE ACTION**

Dear Examiner Jiang:

FILED:

Applicants intend this as a full response to the Examiner's 7 May 2003 Non-Final Office Action.

**08/06/2004** FPATTEMS 00050001 501518 00827453

01 FC:1201 02 FC:1202

258.00 ba 54.00 ba the art knowledge at the time. The data in the attached figure shows that one bisphosphonate had little toxicity and the NSAID had moderate, but when co-administered by different administration pathways, the mixture had a GI toxicity 10 or more times higher for the bisphosphonate and several time higher for the NSAID when taken separately.

Applicant, therefore, believes that the combination of Daifotis et al. and any Lichtenberger NSAID reference does not render the present invention obvious because the Daifotis et al. does not support the combination and neither does the Lichtenberger references. These references simply do not suggest combining the teaching nor do they suggest that outcome of the combination. In fact, Daifotis et al. can be fairly read as teaching squarely away from such a combination. Daifotis et al. states and claims a cure to the basic problem the Examiner now believes Daifotis et al. suggest should be cured by adding a phospholipid, but this contention flies fully in the face of the Daifotis et al. teaching – ordinary artisan look no farther for we have eliminated this problem. Such a statement teaches squarely away from the present invention – the problem is solved.

Applicant, therefore, respectfully requests withdrawal of this rejection as one of ordinary skill in the art would fairly view Daifotis et al. as teaching away from solving a solved problem, a problem Daifotis et al. indeed claims to have solved. Moreover, the combination of all three references does not suggest the combination and in fact the inclusion of Hovancik et al. further demonstrate the total unpredictability of drug combinations.

Applicant has also added new claims 46-48 which add the additional limitation that the two components are in their zwitterionic form. Nothing in Daifotis et al. suggests anything associated with phospholipids and further does not suggest that both compounds be in their zwitterionic form in the composition prior to administration. Applicant therefore request allowance of these new claims.

The Commissioner is authorized to charge any additional fees or credit any overpayments to Deposit Account No. 501518.

If it would be of assistance in resolving any issues in this application, the Examiner is kindly invited to contact applicant's attorney Robert W. Strozier at 713.977.7000

Date: October 7, 2003

Robert W. Strozier, Reg. No. 34,024